



K082675

CONFIDENTIAL

Attachment – 6

510(k) SUMMARY

OCT 1 0 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

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Contact Person: Umberto V. Parrotta

Date Prepared: September 11, 2008

Name of Modified Device and Name/Address of Sponsor:

STA-R® Evolution/Expert Series or STA-R®

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Common or Usual Name:

- IVD Coagulation Device/Instrument.
- Automated and Semi-Automated Hematology Device.
- Multi-Parametric Analyzer

Classification Name:

System, Multipurpose for In Vitro Coagulation Studies

Predicate Devices:

- Diagnostica Stago's STA-R® Automated Multi-Parametric Analyzer (K983460).

Purpose of the Special 510(k) Notice:

- The STA-R® Evolution is a modification to the company's own legally marketed device, STA-R®.

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- The modification of the device involves the upgrade of the instrument's operating system from Windows NT to the Windows XP platform. Slight modifications to the application software were made to accommodate the new operating system along with operator/user enhancements but without logic configuration changes.

Indication/Intended Use:

The STA-R® Evolution (or STA-R®) Automated Multi-Parametric Analyzer is a fully automatic clinical instrument indicated and intended for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

Technological Characteristics:

The STA-R® Automated Multi-Parametric Analyzer is designed as a fully automatic system. Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis, and reporting of results are performed automatically. A central processing unit controls instrument functions such as, management of patient results, quality control, system supervision, support for instrument maintenance, and work load optimization. The STA-R® Evolution is the modified or updated version of the company's STA-R®, legally marketed predicate device. The modification of the device involves the upgrade of the instrument's operating system from Windows NT to the Windows XP platform. Slight modifications to the application software were made to accommodate the new operating system along with operator/user enhancements but without logic configuration changes.

The instrument utilizes Diagnostica Stago reagents in addition to open adaptation of other currently available reagents. Barcoding of test reagents, calibrators, and controls facilitate their use on the system and permits reagent management simple. Manual entry of reagent information enables the use of non-barcoded reagents.

The instrument performs multiple test methodologies in random access as selected by the user. These include clotting time or clot-based tests (i.e. chronometric) measurements and photometric assays (at specific wave lengths) on plasma samples. The Technological Characteristics and Principles of Operation for the aforementioned analyses are the same between the subject submission device and the predicate device.



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Substantial Equivalence:

The STA-R® Evolution has the same intended use and indications, principles of operation, and technological characteristics as the STA-R® (K983460) predicate device. The differences in the operating system software and slight operator/user enhancements to the instrument's application software do not raise any new questions of safety or effectiveness. The Risk Assessment and validation study demonstrate that the STA-R® Evolution is as safe and effective as the predicate device. Thus, the STA-R® Evolution is substantially equivalent to its predicate devices.



OCT 10 2008

Diagnostica Stago, Inc.
c/o Mr. Umberto Parrotta
Director of Regulatory Affairs & Quality Assurance
5 Century Drive
Parsippany, NJ 07054

Re: k082675

Trade/Device Name: STA-R® Evolution /Expert Series Automated Multi-Parametric Analyzer
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: September 12, 2008
Received: September 15, 2008

Dear Mr. Parrotta:

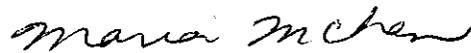
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure



Indications for Use Form

510(k) Number (if known): K082675

Device Name:

STA-R® Evolution/Expert Series Automated Multi-Parametric Analyzer

Indications for Use:

The STA-R® Evolution/Expert Series is a fully automatic clinical instrument designed for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use _____

Maria M. Chan (Optional Format 1-2-96)
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K082675